

## REMARKS

The Office Action dated December 19, 2000 has been carefully reviewed and the foregoing amendments to the application have been made in consequence thereof. Claim 17 has been cancelled. Claims 1, 2, 7-10, 12-16 and 18 have been amended in order to advance the prosecution of this application. Claims 1-16 and 18 remain active in this application.

The Examiner rejected claims 1-18 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claims 1, 9 and 14 have been amended to particularly point out how "treating" results in a recovered solution containing the polypeptide. The claims, as amended, describe such treating as including the steps of mixing the sample with acid, incubating the mixed sample and acid, and clarifying the mixed sample and acid to yield the recovered solution.

Claims 2, 10 and 15 have been amended to correct the recitation of "SEQ ID NO:" as suggested by the Examiner.

Claims 8, 13 and 18 have been amended to indicate "fibers of polypeptides" as suggested by the Examiner, and to add a preamble.

Claims 7, on which Claim 8 depends, 12, on which Claim 13 depends, and 16, on which Claim 18 depends, have been amended to include steps associated with manipulating the solution, as suggested by the Examiner. Such manipulating includes purifying the solution, and concentrating the purified solution.

The amended claims are supported by the Examples which are described in the specification.

Therefore, in view of the amendments described above, Claims 1-16 and 18 do particularly point out and distinctly claim the invention.

The Examiner rejected Claims 1, 3-9, 11-14 and 16-18 under 35 U.S.C. 102(b) as being anticipated by Lombari et al.

Claims 1, 9 and 14 have been amended to describe the acid as consisting essentially of an organic acid.

The Examiner states that Lombari et al. teaches a method of purifying silk proteins. However, Applicants suggest that Lombari does not teach purifying, but does teach solubilizing. A purification requires the isolation of a molecule from a complex mixture of contaminating molecules, i.e. silk protein or outer membrane protein from a cell and all of its constituents. Solubilization is simply reconstituting a substance in its entirety (in the case of Lombari et al. the substance is a spider silk fiber or the glandular secretion of the ampullate gland) into soluble fractions. Examples 6-8 in Lombari et al. use affinity chromatography, which is very different from Applicants' method. Lombari et al. uses a 50-50% volume ratio of organic acid and hydrochloric acid, which is not an organic acid, for recovering a protein. In the method taught by Lombari et al., the protein is only recovered from natural fibers and gland secretions. Lombari et al. discusses a method to solubilize native spider silk proteins solely for the purpose of amino acid composition and N-Terminal sequencing.

Applicant teaches treating a sample with an acid consisting essentially of an organic acid, which is not taught by Lombari et al.; but rather Lombari et al. teaches an

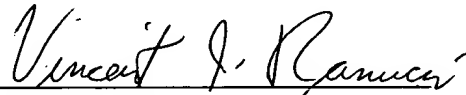
acid consisting essentially of a 50-50% volume by volume ratio of propionate and hydrochloric acid, which is not an organic acid. Applicants' method is for purification and fiber spinning. The method of Lombardi et al. is for amino-acid sequencing (please see column 3, lines 37-46), and is not for purification and fiber spinning.

In view of the foregoing amendments and remarks, it is believed that Claims 1-16 and 18 in this application are allowable, and a Notice to that effect is respectfully solicited.

Should the Examiner wish to contact the Applicants' attorney regarding this application, the Examiner is respectfully invited to do so by calling or writing the undersigned at Office of Counsel, U.S. Army Soldier and Biological Chemical Command, Natick, MA 01760 at (508) 233-4510.

Respectfully submitted,

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1. (Amended) A method, comprising:
  - a. providing: i) a biological sample comprising one or more structural polypeptides; and ii) an acid consisting essentially of an organic acid;
  - b. treating said sample with said acid under conditions such that said one or more polypeptides is recovered in a solution, said treating comprising mixing said sample with said acid, incubating said mixed sample and acid, and clarifying said mixed sample and acid to yield a recovered solution.
2. (Amended) The method of Claim 1, wherein said polypeptide is selected from SEQ ID NO[:]: 2, SEQ ID NO[:]: 4, SEQ ID NO[:]: 6, SEQ ID NO[:]: 8, SEQ ID NO[:]: 9, and SEQ ID NO[:]: 11.
7. (Amended) The method of Claim 1, further comprising the step of manipulating said solution under conditions that insoluble fibers are produced[.], said manipulating comprising purifying the solution, and concentrating the purified solution.
8. (Amended) The [fibers produced according to the process] method of Claim 7, wherein fibers of polypeptides are produced.
9. (Amended) A method, comprising:
  - a. providing: i) host cells expressing one or more recombinant structural polypeptides, and ii) a solution [comprising] consisting essentially of an organic acid;
  - b. treating said host cells with said solution to create a mixture;
  - c. removing insoluble material from said mixture; and

- d. recovering said one or more recombinant polypeptides in a solution[.],  
whereby said treating comprises mixing said cells with said acid,  
incubating said mixed cells and acid, and clarifying said mixed cells  
and acid to yield a recovered solution.
10. (Amended) The method of Claim 9, wherein said one or more polypeptides is  
selected from SEQ ID NO[.]: 2, SEQ ID NO[.]: 4, SEQ ID NO[.]: 6, SEQ ID  
NO[.]: 8, SEQ ID NO[.]: 9, and SEQ ID NO[.]: 11.
12. (Amended) The method of Claim 9, wherein said recovered one or more  
recombinant polypeptides in said solution are manipulated under conditions  
such that insoluble fibers are produced[.], said manipulated comprising  
purifying the solution, and concentrating the purified solution.
13. (Amended) The [fibers produced according to the process] method of Claim  
12, wherein fibers of polypeptides are produced.
14. (Amended) A method, comprising:
- a. providing: i) bacterial cells expressing one or more recombinant  
structural polypeptides, and ii) a solution [comprising] consisting  
essentially of an organic acid selected from formic acid, acetic acid,  
propionic acid, butyric acid, and valeric acid;
  - b. treating said bacterial cells with said solution to create a mixture;
  - c. removing insoluble material from said mixture; and
  - d. recovering said one or more recombinant polypeptides in a solution,  
said treating comprising mixing said cells with said acid, incubating

said mixed cells and acid, and clarifying said mixed cells and acid to yield a recovered solution.

15. (Amended) The method of Claim 14, wherein said one or more polypeptides is selected from SEQ ID NO[: 2, SEQ ID NO[: 4, SEQ ID NO[: 6, SEQ ID NO[: 8, and SEQ ID NO[: 11.
16. (Amended) The method of Claim 14, further comprising the step of manipulating said recovered one or more recombinant polypeptides under conditions such that insoluble fibers are produced[.], said manipulating comprising concentrating said recovered one or more recombinant polypeptides to create a concentrated solution; and forcing said concentrated solution through a spinneret.
18. (Amended) The [fibers produced according to the process] method of Claim 17, wherein fibers of polypeptides are produced.